

**Before the
FOOD AND DRUG ADMINISTRATION
Washington, D.C.**

**In re: Petition for Health Claim:
Vitamin E Dietary Supplements and
Heart Disease**

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Docket No. 99P-4375

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SUPPLEMENTAL SUBMISSION

Julian M. Whitaker, M.D.; Pure Encapsulations, Inc.; Durk Pearson and Sandy Shaw; and the American Preventive Medical Association (collectively, "Health Claim Petitioners") hereby supplement the record in the above-referenced proceeding with the attached exhibits, including the "Analysis of the Economic Impact of FDA Prohibition of Proposed Health Claims" by Economist Paul H. Rubin of Emory University (Exhibit A). The report is submitted in advance of the November 24, 2000, deadline set by the agency (and ordered by the U.S. District Court) for completion of a further evaluation of the above-referenced claim following FDA's January 11, 2000 denial of the claim. See Exhibit B. It is designed to aid the agency in comprehending the economic impact of the barriers it has erected to communication of truthful, qualified claims. This submission is particularly warranted in light of FDA's decision to include economic analysis as a justification for the suppression of another health claim (the Saw Palmetto/mild BPH claim in Docket No. 99P-3030) in a letter from CFSAN Director Levitt dated May 26, 2000 at 10, yet not invite comments on the point in the agency proceedings antedating issuance of the letter.

In his Report, Professor Rubin explains that FDA's December 22, 1999 Guidance for Industry on Significant Scientific Agreement effectively requires an NDA or NDA-equivalent degree of scientific proof as a condition precedent to health claim approval.

99P-4375

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Professor Rubin explains that to conduct research necessary to meet such a level of proof would impose costs between \$58 million and \$345 million on health claim petitioners for each claim they wish to make. He further explains that no company in the dietary supplement industry has the financial wherewithal to afford that kind of expenditure. The attached affidavits from the Health Claim Petitioners confirm that they do not have the financial wherewithal to afford such costs. See Exhibit C. Professor Rubin explains that products of nature, such as the dietary supplement that is the subject of the above-referenced proceeding, are unpatentable. Thus, unlike pharmaceutical companies' patented products, the Health Claim Petitioners' unpatentable ones cannot enjoy monopoly rents, above market rates of return, needed to recoup a \$58 million to \$345 million investment. It is therefore the case that FDA's requirement of near conclusive proof (an NDA or NDA-equivalent degree of proof) effectively prohibits the communication of truthful health claim information on the labels and in the labeling of dietary supplements. Dr. Rubin concludes that the agency's regime taxes truthful speech out of the marketplace and helps foster a "black market" in untrue information that reduces consumer welfare:

... [T]he FDA's position is equivalent to requiring a large payment to allow a firm to exercise its free speech rights. Since no one will find it worthwhile to undertake this investment, as discussed above, the FDA's tax is a prohibitive tax, and will effectively tax some truthful speech out of the market. That is, the effect will be to suppress truthful speech.

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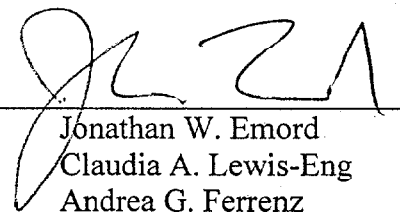
If consumers desire health information about supplements but legitimate sellers are denied the right to provide such information, then a "black market" in untrue information may develop. As a result, consumers may ultimately use less healthful products. In either case, the result will be reduced health for consumers. Rather than improving the market for information, the FDA's actions have effectively shut down part of this market.

For the foregoing reasons, and those previously articulated by the Health Claim Petitioners, this agency must end its legacy of suppressing health claims by favoring disclosure over suppression in every instance where a claim can be rendered nonmisleading through the addition of appropriate disclaimers. It must give consumers at the point of sale access to truthful information upon which to make informed, healthful choices. The agency's speech suppression not only violates the First Amendment rights of the Health Claim Petitioners, it violates those same rights of consumers and it sacrifices the health of all Americans.¹

Respectfully submitted,

JULIAN M. WHITAKER, M.D.;
PURE ENCAPSULATIONS, INC.;
DURK PEARSON and SANDY SHAW;
AMERICAN PREVENTIVE MEDICAL
ASSOCIATION,

By:



Jonathan W. Emord
Claudia A. Lewis-Eng
Andrea G. Ferrenz

Their Counsel

Emord & Associates, P.C.
1050 Seventeenth Street, N.W.
Suite 600
Washington, D.C. 20515
P: (202) 466-6937
F: (202) 466-6938
e-mail: emordall@erols.com

Dated: August 8, 2000

¹ In certain instances, e.g., FDA's suppression of the folic acid/neural tube defect claim and of the B-vitamin/vascular disease claim, this agency's suppressive acts have had monstrous consequences, sacrificing life (in the form of 2,500 preventable neural tube defect births each year and countless preventable increased risks of vascular disease).

EXHIBIT A

ANALYSIS OF THE ECONOMIC IMPACT OF FDA PROHIBITION OF PROPOSED HEALTH CLAIMS

Paul H. Rubin
Department of Economics and School of Law
Emory University
Atlanta, GA 30322-2240
Voice: 404-727-6365
Fax: 630-604-9609
Email: prubin@Emory.edu
<http://www.Emory.edu/COLLEGE/ECON/Rubi.htm>

This is an analysis of the economic impact of the FDA refusal to authorize one or more of the health claims pending before the agency, and instead to compel as a condition for approval an NDA or NDA-equivalent degree of proof for these claims.

The nutrients in question are: 1) Three B vitamins (folic acid, B6 and B12) considered together for reduction of vascular disease; 2) Vitamin E for reduction of heart disease; 3) Folic Acid for reducing neural tube defects; 4) Omega-3 Fatty Acids for reduction of coronary heart disease risk; 5) Antioxidants (Vitamins A, C, E, beta-carotene, lycopene and lutein) for reduction of cancer risk; and 6) Fiber for reduction of colorectal cancer. The proposed health claims (perhaps with appropriate disclaimers) are: 1) "As part of a well-balanced diet, rich in fresh whole fruits and vegetables, daily intake of at least 400 ug of folic acid, 3 mg of vitamin B6, and 5 ug of vitamin B12 may reduce the risk of vascular disease;" 2) "As part of a healthy diet low in saturated fats and cholesterol, 400 IU/day of Vitamin E (d- α -tocopherol or dl- α -tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.¹" 3) ".8 mg of folic acid in a dietary supplement is more effective at reducing neural tube defects than a lower amount in foods in common form;" 4) "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease;" 5) "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer;" and (6) "Consumption of fiber may reduce the risk of colorectal cancer."

In performing this analysis, I use the standard of maximization of consumer welfare, the general standard used by economists in evaluating public policy decisions.

Professional Background

I am a Professor of Economics and Law at Emory University in Atlanta and editor in chief of *Managerial and Decision Economics*. I am an Adjunct Scholar at the American Enterprise Institute and the Georgia Public Policy Foundation; former Vice President of the Southern Economics Association; and a Fellow of the Public Choice Society. I have been Senior Staff Economist at the President's Council of Economic Advisers, Chief Economist at the U.S. Consumer Product Safety Commission, Director of Advertising Economics at the Federal Trade Commission, and vice-president of Glassman-Oliver Economic Consultants, Inc., a litigation consulting firm in Washington. I have taught economics at the University of Georgia, City University of New York, VPI, and George Washington University Law School. I have written or edited seven books, and published over one hundred articles and chapters on economics, law, and regulation, in journals including the *American Economic Review*, *Journal of Political Economy*, *Quarterly Journal of Economics*, *Journal of Legal Studies*, *Journal of Law and Economics*, and the *Yale Journal on Regulation*, and I sometimes contribute to the *Wall Street Journal* and other newspapers. My work has been cited in the professional literature over 1300 times. Recent books include *Managing Business Transactions*, Free Press, 1990 and *Tort Reform by Contract*, AEI, 1993. I have consulted widely on litigation and regulation related matters, and have addressed numerous business, government, professional, policy and academic audiences. I received my B.A. from the University of Cincinnati in 1963 and my Ph.D. from Purdue University in 1970.

I have written several professional journal articles on the regulation of information by the FDA. I wrote one of the first articles advocating direct-to-consumer advertising,² and the FDA cited this article in its decision to remove the moratorium on this form of advertising. I have also written articles advocating removal of the requirement for the "brief summary" on television advertising,³ and this policy has also been adopted. I testified before the FDA on the beneficial effects of this policy, and the FDA has chosen to continue the policy.

¹ There are also proposed labels for d- α -tocopherol and dl- α -tocopherol separately.

² Alison Masson and Paul H. Rubin, "Matching Prescription Drugs and Consumers: The Benefits of Direct Advertising," *New England Journal of Medicine*, Aug. 22, 1985, 513-5; also, "Reply," Feb. 20, 1986, 524.

Investment in Pharmaceutical Research

The FDA has required a degree of proof to support health claim approval for supplements that is equivalent to the degree of proof required for approval of new pharmaceuticals:

A causal relationship exists when data show that the consumption of a substance increases or decreases the probability of developing or not developing a particular disease or health-related condition. Causality can be best established by interventional data, particularly from randomized, controlled clinical trials, that show that altering the intake of an appropriately identified and measured substance results in a change in a valid measure of a disease or health-related condition. In the absence of such data, a causal relationship may be inferred based on observational and mechanistic data through strength of association, consistency of association, independence of association, dose-response relationship, temporal relationship, effect of dechallenge, specificity, and explanation of a pathogenic mechanism or a protective effect against such a mechanism (biological plausibility). Although these features strengthen the claim that a substance contributes to a certain health outcome, they do not prove that eating more or less of the substance will produce a clinically meaningful outcome. In many cases (for example, if the intake of the substance has not been or cannot be assessed adequately in available observational studies because it has not been commonly consumed or its intake cannot be assessed independently of other substances), controlled clinical trials are necessary to establish the validity of a substance/disease relationship.⁴

This level of proof is essentially equivalent to the requirement of the new drug approval (NDA) process that pharmaceuticals must undergo for approval. Indeed, for two of the claims at issue, the FDA has made this explicit. For the claims involving three B vitamins (folic acid, B6 and B12) considered together for reduction of vascular disease the FDA has specifically indicated that "These findings strongly suggest that well designed and controlled clinical studies are necessary to establish whether folic acid, vitamin B6 and vitamin B12 may reduce the risk of vascular disease."⁵ Similarly, for

³ Paul H. Rubin, "Economics of Prescription Drug Advertising," *Journal of Research in Pharmaceutical Economics*, 1991, 29-41.

⁴ U. S. Food and Drug Administration, Center for Food Safety and Applied Nutrition Office of Special Nutritionals, December 22, 1999, Guidance for Industry Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements, available at <http://vm.cfsan.fda.gov/~dms/ssaguide.html>, p. 14-15, Online version.

⁵ Letter of November 30, 1999, from Elizabeth A. Yetley, Director, Office of Special Nutritionals, Center for Food Safety and Applied Nutrition, FDA, to Jonathan W. Emord, regarding Petition for Health Claim: Folic Acid, Vitamin B6, and Vitamin B12 Dietary Supplement and Vascular Disease, p. 11.

claims involving Vitamin E and heart disease, the FDA has indicated that "One reason for the insufficient evidence from the primary prevention studies is that none of the studies were designed to measure the association between Vitamin E and reduced risk of CVD."⁶ Thus, it is apparent that the FDA now requires a level of proof for health claims equivalent to that required for pharmaceuticals.

However, the economics of the drug approval process and of the nutritional supplements industry, and the requirements of patent law, interact in such a way that no one will obtain such approval. Therefore, should the FDA require such a standard for approval, the result would be that the health claims would not be made. The basic point is this: Drug approval or its equivalent is quite expensive. Naturally occurring products such as those at issue here, which have been in use for a substantial period of time, cannot be patented. The supplement industry is highly competitive. Therefore, there is no way for any producer to earn a return on the investment that would be needed to obtain approval, and so no producer would spend the resources to obtain such an approval. Therefore, the effect of an FDA decision would not be to induce producers to undertake the research needed to obtain approval. It would merely be to deny consumers the valuable information that would be available if the health claims could be made. I now develop this analysis in detail.

Costs of Drug Approval

Costs of drug approval are quite high. DiMasi and his co-authors provide useful estimates of the costs of drug development.⁷ Their analysis enables me to break down the costs in a way relevant for estimating the expected costs of obtaining approval for supplements, if someone would be willing to undertake such an investment. A major part of the cost of obtaining a new drug approval is the "preclinical" phase, or general research expenditures of pharmaceutical firms, which cannot be attributed to any one drug. In the DiMasi analysis, these costs represent over half of the total expenditures.⁸ I

⁶ Letter of January 11, 2000, from Elizabeth A. Yetley, Director, Office of Special Nutritionals, Center for Food Safety and Applied Nutrition, FDA, to Jonathan W. Emord, regarding Petition for Health Claim: Vitamin E dietary Supplements and Heart Disease, p. 7-8.

⁷ Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski, and Louis Lasagna, "Costs of Innovation in the Pharmaceutical Industry," *Journal of Health Economics*, 10 (1991), 107-142.

⁸ This is because the preclinical expenditures occur very early in the development process, and the capitalization process adds a substantial amount to these costs.

assume that there are no preclinical costs attributable to these products, since the products and their properties are well known.

For new chemical entities (NCEs) that are ultimately approved, the mean clinical period costs (including Phases I, II, and III, and animal studies) is \$43 million, with a 95% confidence interval of \$43; the median is $\$40.9 \pm \11.3 million (that is, from \$29.6 to \$52.2 million), all in 1987 dollars.⁹ If we use the mean, \$43 million, then, in 1999 dollars, this is **\$58 million**. This is the best estimate of the expected cost of approval for a NCE that is ultimately approved.¹⁰ This is the amount per substance that someone would have to be willing to invest to obtain approval. No one would undertake such an investment unless they expected to be able to recoup it. But there is no way in which a producer could expect such recoupment. This is because a) any firm obtaining approval for any of these supplements would be unable to obtain a useful patent; and b) the supplements industry is highly competitive and therefore recoupment of the needed investment would be impossible without a patent.

Many of the six supplements at issue here are aggregations of more than one entity. The B vitamins considered for reduction of vascular disease include folic acid, B6 and B12; the Antioxidants for reduction of cancer risk include Vitamins A, C, E, beta-carotene, lycopene and lutein; and the Fiber for reduction of colorectal cancer includes both soluble and non-soluble fiber. In its consideration of the petition regarding the B vitamins for reduction of vascular risk the FDA considered each vitamin separately.¹¹ I assume therefore that if someone were to seek approval through NDA-level studies, the FDA would require separate analysis for each component. Table 1 indicates the cost of seeking approval for each health claim. These costs range from \$58 million to \$348 million.

⁹ DiMasi et al., p. 130 and Table 7.

¹⁰ The equivalent figure for marketed NCEs is \$75.2 million in 1987 dollars, or \$101.5 million in 1999 dollars. The difference is that this latter figure includes costs of both successful and unsuccessful drugs, with the costs of unsuccessful drugs allocated to successes. I use the lower number for all of the substances at issue. It is possible that some would not be approved, but since this would not be known, I assume that all would be approved. Alternatively, I could use the higher number and infer the probability that some would not be approved; the results would be the same.

¹¹ Letter of November 30, 1999, from Elizabeth A. Yetley, Director, Office of Special Nutritionals, Center for Food Safety and Applied Nutrition, FDA, to Jonathan W. Emord, regarding Petition for Health Claim: Folic Acid, Vitamin B6, and Vitamin B12 Dietary Supplement and Vascular Disease.

Table 1: Estimated Cost of Seeking NDA Level Approval for Each Health Claim

Claim	Cost Of NDA-Level Approval (1999 Dollars)
Three B vitamins considered together for reduction of vascular disease: folic acid, Vitamin B6 and Vitamin B12	\$174 Million
Vitamin E for reduction of heart disease	\$58 Million
Folic Acid for reducing neural tube defects	\$58 Million
Omega-3 Fatty Acids for reduction of coronary heart disease risk	\$58 Million
Antioxidants for reduction of cancer risk: Vitamins A, C, E, beta-carotene, lycopene and lutein	\$348 Million
Fiber for reduction of colorectal cancer: Soluble and non-soluble fiber	\$116 Million

Source: Calculated by author from data in Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski, and Louis Lasagna, "Costs of Innovation in the Pharmaceutical Industry," *Journal of Health Economics*, 10 (1991), 107-142.

Patentability¹²

As to patentability: First, a requirement for receiving a valid patent is that the product be "novel." None of the supplements at issue here are novel. All are readily available from numerous sources and have been available for many years. Obviously, a product that has been in use for decades cannot be novel. Additionally, patent laws distinguish between "discovery" and "invention," and only inventions are patentable.¹³

More specifically, "products of nature," are not patentable.¹⁴ Thus, if anyone were to spend the resources needed to obtain approval for these supplements, they could not obtain patent protection. All of these supplements are natural products. The Three B vitamins (folic acid, B6 and B12) are found in many foods; Vitamin E is found in foods; Folic Acid is available in foods; Omega-3 Fatty Acids come from seafoods; Antioxidants are readily available in foods; and Fiber is available from wheat bran and other foods. Thus, all of these supplements are products of nature and not novel, and so are not patentable.

Industry Competitiveness

If a manufacturer of supplements could have protection from competition from sources other than patent law, then the investment in obtaining approval of health claims could be worthwhile. However, there is no source of such protection. The supplements industry is highly competitive. I have a list of 40 companies in the industry and their annual sales for 1997.¹⁵ I have calculated total sales for the 40 firms at \$4,511 billion. The largest firm has sales of \$425 million, about 9% of the total. The largest four firms account for only 30% of the total, a low number and one sign of a competitive industry. More specifically, economists commonly use the HHI index to measure the competitiveness of an industry.¹⁶ I have calculated the HHI for the supplements industry

¹² For a discussion of these issues, a useful source is Shayana Kadidal, "Plants, Poverty, and Pharmaceutical Patents," 103 *Yale Law Journal* 223, October 1993.

¹³ Kadidal, at 238.

¹⁴ Kadidal, at 237.

¹⁵ The Hartman Group, 1998 Industry Overview, *Nutrition Business Journal*, September 1998, 18-19.

¹⁶ This is the Herfindahl-Hirshman Index. It is used by the Federal Trade Commission and the Department of Justice Antitrust Division in evaluating mergers. As defined in the FTC-DOJ 1992 Merger Guidelines (<http://www.ftc.gov/bc/docs/horizmer.htm>), footnote 17: "For example, a market consisting of four firms with market shares of 30 percent, 30 percent, 20 percent and 20 percent has an HHI of 2600 ($30^2 + 30^2 + 20^2 + 20^2 = 2600$). The HHI ranges from 10,000 (in the case of a pure monopoly) to a number approaching

as 445 (Table 2.) Additionally, a private firm called The Vitamin Shoppe lists in their catalog 280 suppliers whose products they carry.¹⁷ Sales are not given, so I cannot use this data to modify the HHI index. However, addition of small firms would reduce the calculated index even further. This is a highly unconcentrated industry.¹⁸ In other words, the supplements industry is competitive.

In a competitive industry, market forces will assure that price will generally be equal to marginal costs. A sunk cost such as the cost of obtaining approval for a NCE will not and cannot effect price. Thus, in this industry, there is no way that any producer who spent the \$58-\$348 million needed to obtain approval would be able to earn this money back. Any firm spending resources to obtain such approval would be forced to price its product at the same price as any firm that did not spend resources obtaining approval, and this price would not reflect the costs of obtaining approval. As a result, no rational firm would spend this money. Therefore, if these claims are not granted, then no research will be performed, and the health claims will not be made.

The assumption made by the FDA in the two letters to Jonathan Emord mentioned in notes 5 and 6 cited above is that if the petition is denied, then manufacturers will seek approval of these nutrients thorough an NDA equivalent process. But this will not occur, for reasons discussed above. Therefore, the effect of denying the petitions will be that fewer consumers will learn of the benefits of the products. Therefore, by denying the petition, the FDA is denying truthful information to the marketplace. If the manufacturers are not allowed to make the desired claims, then the result will be that some consumers will not learn of these benefits, and this will cause a net harm to consumers. This is not a socially desired outcome.

zero (in the case of an atomistic market). Although it is desirable to include all firms in the calculation, of information about small firms is not critical because such firms do not affect the HHI significantly."

¹⁷ August 2000 Catalog, available from The Vitamin Shoppe, 4700 Westside Ave., North Bergen, New Jersey, 07407, 800-223-1216.

¹⁸ "The Agency divides the spectrum of market concentration as measured by the HHI into three regions that can be broadly characterized as unconcentrated (HHI below 1000), moderately concentrated (HHI between 1000 and 1800), and highly concentrated (HHI above 1800)." (Merger Guidelines.)

Table 2: Calculation of HHI for Supplements Industry

Sales, \$millions	Sales/Total sales (4511)	Percentage of Total (x100) Squared
\$425	.09	81
340	.08	64
325	.07	49
291	.06	36
281	.06	36
260	.06	36
219	.05	25
213	.05	25
170	.04	16
152	.03	9
120	.03	9
110	.02	4
109	.02	4
108	.02	4
100	.02	4
98	.02	4
90	.02	4
90	.02	4
88	.02	4
70	.02	4
70	.02	4
65	.01	1
55	.01	1
50	.01	1
50	.01	1
50	.01	1
49	.01	1
45	.01	1
43	.01	1
40	.01	1
40	.01	1
35	.01	1
35	.01	1
34	.01	1
34	.01	1
33	.01	1
32	.01	1
32	.01	1
30	.01	1
30	.01	1
\$4511 Total Sales		445 HHI

Source: Calculated from The Hartman Group, 1998 Industry Overview, *Nutrition Business Journal*, September 1998, 18-19.

A Tax on Speech

Petitioners in this matter and other manufacturers of legitimate and legal food supplements desire to make true health claims for these products. There are many true claims that can be made about these supplements without having the supplements undergo an NDA or NDA-equivalent process. The FDA desires to allow only two levels of claims: either no claim at all, or a claim supported by NDA-level documentation. But there are many true statements that can be made with a lesser amount of proof. Manufacturers do not desire to make untruthful statements, or to claim a higher level of proof for their statements than is appropriate. Rather, they desire to make claims that are supported by the available evidence. For example, most of the claims at issue here include the word "may," so that these are hedged and nuanced claims. Moreover, manufacturers have expressed willingness to include further disclaimers if the FDA decides that these are needed. Indeed, the court in *Pearson v. Shalala* itself provided some suggestions for disclaimers.¹⁹

A requirement for an NDA-level of proof before allowing any claim at all is equivalent to imposing a tax of \$58-\$348 million on truthful speech. That is, the FDA's position is equivalent to requiring a large payment to allow a firm to exercise its free speech rights. Since no one will find it worthwhile to undertake this investment, as discussed above, the FDA's tax is a prohibitive tax, and will effectively tax some truthful speech out of the market. That is, the effect will be to suppress truthful speech.

Of course, this also means that consumers will be denied the right to hear truthful statements about these products. One result will be that consumers will simply have less true information about supplements. Another result may be that unscrupulous sellers may provide untrue or fraudulent information about some supplements or nutrients. If consumers desire health information about supplements but legitimate sellers are denied the right to provide such information, then a "black market" in untrue information may

¹⁹ *Durk Pearson And Sandy Shaw, American Preventive Medical Association and Citizens For Health, Appellants V. Donna E. Shalala, Secretary United States Department Of Health And Human Services, et al., Appellees, For the District of Columbia Circuit, Argued December 1, 1998, Decided January 15, 1999, No. 98-5043 Consolidated with 98-5084, Appeals from the United States District Court for the District Of Columbia (95cv01865).*

develop. As a result, consumers may ultimately use less healthful products. In either case, the result will be reduced health for consumers. Rather than improving the market for information, the FDA's actions have effectively shut down part of this market.

Summary

The FDA in denying the several petitions has assumed that manufacturers will seek approval for these nutrients under an NDA-equivalent process. But the economics of the drug approval process and the supplement industry and the requirements of patent law interact in a way to ensure that no one will find it worthwhile to seek such approval. Rather, the result of denying the petitions is that consumers will simply be denied valuable and beneficial information about useful preventatives. The FDA has imposed a tax on truthful speech, and the level of the tax is sufficiently high so as to be prohibitive. The FDA has closed part of the market for true information, and this will result in reduced health for consumers.

PAUL H. RUBIN

August 8, 2000

Department of Economics
Emory University
324 Rich Building, 1602 Mizell Drive
Atlanta, GA 30322-2240
U.S. Citizen

Office: (404) 727-6365
Home: (404) 814-0081
Fax: (404) 727-4639
email: prubin@emory.edu
<http://www.emory.edu/COLLEGE/ECON/Rubi.htm>

EDUCATION

Ph.D., Economics, Purdue University, 1970
B.A., University of Cincinnati, 1963 (Honors)

PROFESSIONAL EXPERIENCE

ACADEMIC

Professor of Economics and Law, Emory University, beginning 1999; Professor of Economics, 1991-1999; Acting Chair, Economics, 1993-94.
Adjunct Professor: VPI, 1984; George Washington University Law Center, 1985-89.
Professor, Baruch College and the Graduate Center, CUNY, 1982-83.
Assistant, Associate and Full Professor of Economics, University of Georgia, 1968-82.

NONACADEMIC

Vice President, Glassman-Oliver Economic Consultants, 1987-1991.
Chief Economist, U.S. Consumer Product Safety Commission 1985-87 (Senior Executive Service).
Director of Advertising Economics, Federal Trade Commission, 1983-85.
Senior Staff Economist, President's Council of Economic Advisers, 1981-82.

ADDITIONAL PROFESSIONAL AFFILIATIONS

Adjunct Scholar: American Enterprise Institute; Georgia Public Policy Foundation; Cato Institute, 1992-1998.
Editor In Chief: *Managerial and Decision Economics*.

RESEARCH AND TEACHING AREAS

Law and Economics (Economics Departments, Law Schools, and Practicing Attorneys); Industrial Organization and Antitrust; Transactions Cost Economics; Government and Business (Economics and MBA Students); Public Choice; Economics of Advertising and Safety; Regulation and Cost-Benefit Analysis; Price Theory; Law in Post-Communist Economies; Biological Evolution and Economics.

PROFESSIONAL RECOGNITION

Over 1300 citations to published work in *Social Science Citation Index*; about 60-75 per year.

"Why Is the Common Law Efficient?" *Journal of Legal Studies*, 1977, over 250 citations; Reprinted seven times, in English, Spanish and French.

"Self Interest, Ideology and Logrolling in Congressional Voting," *Journal of Law and Economics*, 1979, with James Kau, over 160 citations; Reprinted once.

"The Theory of the Firm and the Structure of the Franchise Contract," *Journal of Law and Economics*, 1978, over 120 citations; Reprinted once.

Listed in *Who's Who in Economics, A Biographical Dictionary of Major Economists*, Second Edition, edited by Mark Blaug, Cambridge: MIT Press, 1986; Third Edition, edited by Simon James and Mark Blaug, Hants, UK: Edgar Elgar Publishing, Limited, 1998. These volumes include the 1000 most cited living and 400 deceased economists. Living economists citations determined from the *Social Sciences Citation Index*.

Listed in: *Who's Who in the World*, *Who's Who in the East*, *Who's Who in the South and Southwest*, *Who's Who in Finance and Industry*, *Who's Who in Science and Engineering*, *Dictionary of International Biography*; *Men of Achievement*; *Heritage Guide to Public Policy Experts*; *Cato Policy Experts*; *FACSNET Economic Experts*.

Grants and Fellowships: Emory University International Travel Fund, 1998; 2000; Emory University Research Committee, 1997; William H. Donner Foundation, 1997-98; Pfizer, 1997; IRIS (University of Maryland, funded by USAID), 1992-93; Paul Orefice Fund, AEI, 1993; Liberty Fund, 1979; CUNY, 1983.

Fellow, Public Choice Society

Member, Institute of Justice task force on "Consumer Freedom"

Asked to write entries for *Encyclopedia of Law and Economics* and for *New Palgrave Dictionary of Economics and the Law*.

Senior lecturer, World Bank Conference on Private Sector Development, Trest, Czech Republic, November 1994.

First Vice-President, Southern Economics Association, 1994-1996

Vice-President, Georgia Chapter, National Association of Scholars, 1994-2000.

Chairman's Award, Consumer Product Safety Commission, 1987.

Managing Business Transactions, 1990; paperback, 1993

Reviews: *Journal of Economic Literature*, June, 1992, by David Kaserman, 900-1; *Southern Economic Journal*, July, 1992, by Dwight Lee, 131-132; *Managerial and Decision Economics*, January, 1993, by Gregory Dow, 91-93; *Across the Board*, January, 1991, by Shlomo Maital; *Booklist*, November, 1990; *Journal of Business Communications*, 1993, by Donald P. Rogers, p. 84-85; *Sloan Management Review*, Winter, 1991; *Personal Selling Power*, March, 1991; *Manageris* (French), 1994, by Bernard Sinclair-Desgagne.

Several course adoptions; selected by the Executive Book Club.

Guest editor, special issue of *Managerial and Decision Economics*, March 1993, stimulated by *Managing Business Transactions*.

Tort Reform by Contract, reviewed, *Journal of Legal Economics*, July 1998, by Thomas Ireland, 96-98.

PUBLICATIONS

BOOKS:

Written:

1. *Congressmen, Constituents, and Contributors*, Nijhoff, 1982, with James B. Kau.
2. *Business Firms and the Common Law*, Praeger, 1983
3. *Managing Business Transactions: Controlling the Costs of Coordinating, Communicating, and Decision Making*, Free Press, Foreword by Oliver Williamson, 1990; paperback, 1993.
4. *Tort Reform by Contract*, American Enterprise Institute, 1993.
5. *Promises, Promises: Contracts in Russia and Other Post-Communist Economies*, Shaftesbury Papers (No. 11), Edward Elgar and the Locke Institute, 1998.

Edited:

1. *Evolutionary Models in Economics and Law*, (Central paper by Jack Hirshleifer), Vol. 4 of *Research in Law and Economics*, 1982.
2. *Deregulating Telecommunications: The Baby Bells Case for Competition*, Wiley, 1995, (with Richard Higgins).

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8. Letter, *Commentary*, May 1994.
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OTHER PROFESSIONAL ACTIVITIES

PARTICIPATION IN PROFESSIONAL MEETINGS

American Association of Law Schools, 1985.
American Economics Association/Allied Social Science Associations, 1979, 1980, 1981, 1984, 1993, 1994, 1995, 1996, 1997, 1998, 1999.
American Law and Economics Association, 1993, 1994, 1995, 1996, 1997, 1998, 1999.
Association for Politics and the Life Sciences, 1999.
Canadian Law and Economics Association, 1999.
Econometric Society, 1970, 1971, 1974, 1975, 1977, 1978; European Meetings, 1978.
European Law and Economics Association, 1993, 2000.
International Society for Human Ethology, 2000.
International Society for New Institutional Economics, 1998.
Public Choice Society, 1977, 1978, 1979, 1980, 1981, 1983, 1985, 1989, 1992, 1993, 1994, 1996, 1998, 1999.
Society for Evolutionary Analysis in Law, 2000.
Southern Economic Association, 1971, 1976, 1977, 1978, 1979, 1980, 1981, 1984, 1985, 1987, 1991, 1993, 1994, 1995, 1996, 1997, 1998.
Southern Political Science Association, Invited Panel, 1998.
Western Economic Association, 1974, 1975, 1984, 1985, 1988, 1996, 1997.

CONFERENCE ORGANIZED

"Economics of Consumer Protection," Georgetown University, Continuing Legal Education, 1985.

INVITED PRESENTATIONS AND CONFERENCES

Presentations at Universities

Arizona State University, 2000; Auburn University, 1978, 1996; Berkeley, 1984; Boston University, 1984; Carnegie-Mellon, 1982; Case-Western Reserve University, 1986; CIRANO (Montreal), 1996; Clemson University, 1993; Columbia University, 1998; Cornell University, 1998; Duke University, 1981; Emory University, 1981; Florida State University, 1998; George Mason University, 1983, 1985, 1989, 1990, 1992, 1993, 1994, 1995, 1997, 1998; Harvard University, 1993, 1995; Hoover Institution, 1983; Lund University (Sweden), 1992; Montana State University, 1998; McMaster University, 1983; New York University, 1998; Northwestern University, 2000; Purdue University, 1991; Stanford University, 1995; Texas A & M, 1985; University of Chicago, 1978, 1979; University of Florida, 1989; University of Georgia, 1996; University of Kansas, 1995; University of Miami, 1979; University of Michigan, 1987; University of Pennsylvania, 1993; University of Toronto, 1984, 1995; Virginia Polytechnic Institute, 1983; Washington University, 1991, 1993; Western Ontario, 1984; York University, 1984.

Non-Academic Presentations

Federal Trade Commission, 1983; Cato Institute, 1985, 1990, 1991; U.S. Department of Justice, Antitrust Division, 1986, 1988, 1995; National Association of Business Economists, 1988; Brookings Institution, 1986; American Medical Writers-Pharmaceutical Advertising Association, 1986; National Library of Medicine, 1986; American National Standards Institute, 1986; Jefferson Society, 1986; Drug Information Association, 1991; U.S. Commodities Futures Trading Commission, 1991, Distinguished Speaker, 1992; U.S. Chamber of Commerce, Washington, 1991; Milken Institute, 1992; Food and Drug Law Institute, 1992; Institute for International Research, 1992; Heritage Foundation, 1992; American Enterprise Institute, 1992, 1993, 1994, 1995; Coalition of Healthcare Communicators, 1992; Independent Institute, 1993, 1994; Political Economy Research Center, 1994; Ad-Hoc Committee on Pharmaceutical Economics, 1997; Employer's Managed Health Care Association, 1999; Mercatus Center (Capitol Hill), 2000.

Invited Conference Attendance

Economics of Regulated Utilities, University of Chicago, 1975; Legal Institute for Economists, University of Miami, 1977; Private Alternatives to the Judicial System, University of Miami, 1978; Toward Liberty, VPI, 1978; Evolutionary Theory in Law and Economics, University of Miami, 1980; Guest, Nutter Memorial Lecture, Hoover Institution, 1981; Regulatory Authorities, Corporate Privacy, and the Corporate Attorney, Emory University, 1981; Carnegie Conference on Political Economy, Pittsburgh, 1982, 1983, 1984; Constitutional Economics, Heritage Foundation, 1982; Perspectives on Entrepreneurship, Political Economy Research Center, Denver, 1984; Critical Issues in Tort Law Reform, Yale, 1984; Valuing Health Risks, National Academy of Sciences, 1987; The Calculus of Consent After 20 Years, Santa Cruz, 1988; Political Economy Forum, Political Economy Research Center, Bozeman, Montana, 1990, 1998; Malpractice Reform, American Enterprise Institute, 1992; Health Care Policy and Regulation Workshop, Rutgers, 1994; Franchising, University of Michigan, 1994; Workshop on the Evolution of Utilities and Utility Functions, University College, London, 1997; Evolution and Legal Theory, Georgetown University, 1999.

OUTSIDE PROMOTION AND TENURE REVIEWS: Baruch College, CUNY; Brigham Young; Cornell; George Mason; George Washington; Florida State; Pennsylvania State University at Erie; University of Alabama; University of Kansas; University of Southern California; University of Minnesota; Vanderbilt.

DOCTORAL COMMITTEES CHAIRED:

Susan Griffin, Emory, 1994, (Center for Disease Control); Todd Merolla, Emory, 1995; Kristine Principe, Emory, 1996; Raymond Atkins, Emory, 1998 (J.D., George Mason; Covington and Burling); John Yun, Emory, 1999 (Federal Trade Commission); Kari Jones, Emory, 1999 (University of Georgia); David Prince, 2000 (J.D., University of Michigan; Simpson, Thacher and Bartlett).

EDITORIAL

Editor-in-Chief

Managerial and Decision Economics, since 1994; editor, Special issue, "Transactions Costs and Management," 1993.

Editorial Boards

Public Choice; Regulation; Journal of Bioeconomics; Journal of Research in Pharmaceutical Economics; Journal of Real Estate Finance and Economics.

Referee

National Science Foundation; Research Council of Canada; *American Economic Review; American Journal of Political Science; American Law and Economics Review; American Political Science Review; Annals of Regional Science; Cato Journal; Contemporary Policy Issues; Eastern Economic Journal; Economic Inquiry; Economic Journal; Economics of Governance; Emory University Law Review; European Journal of Law and Economics; International Regional Science Review; International Review of Law and Economics; Journal of Corporate Finance; Journal of Economic Behavior and Organization; Journal of Economics and Business; Journal of Economics and Finance; Journal of Labor Research; Journal of Law and Economics; Journal of Law, Economics, and Organization; Journal of Legal Studies; Journal of Marketing; Journal of Political Economy; Journal of Public Economics; Journal of Real Estate Finance and Economics; Journal of Social and Biological Structures; Journal of the American Real Estate and Urban Economics Association; Managerial and Decision Economics; National Tax Journal; Politics and the Life Sciences; Public Choice; Public Finance Quarterly; Quarterly Journal of Economics; Review of Regional Studies; Social Science Quarterly; Southern Economic Journal; Marketing and Public Policy Conference, 1995.*

CONSULTING

ANTITRUST, INCLUDING MERGERS AND ACQUISITIONS

Appelton Papers; ARCO; Barclays Bank and Visa; Broadcast Music Inc.; Browning-Ferris Industries; Campbells; Coca-Cola Bottling Company of the Southwest; College Football Association; Columbian Chemical Company; Dresser Industries; First Hawaiian; Georgia-Pacific; General Motors; Juki; Kodak and Fuqua; Levi Strauss; McKesson; National Soft Drink Association; Nederlander; *Newsday*; *Olivetti*; Professional Golfers Association; Real estate industry, market definition; Regional Bell Operating Companies; Roppe; Sara Lee; Scripps; SmithKline-Beckman; Southern Natural Gas; Thomson; United Airlines; West Point Pepperell.

OTHER MATTERS

Alamo Car Rental; Cemex; Ciba-Geigy; Dial Corp; Drug Emporium; Emerson Electric; for Hernando de Soto, on property rights in the informal sector of the Peruvian economy, cited in *The Other Path*; Ford Motor Company; National Propane Gas Association; Pfizer; Physicians Weight Loss; R.J. Reynolds, on advertising matters; Hedonic damages, several cases; U.S. Sentencing Commission; Texans Against Censorship, Inc.

TESTIMONY

In the U. S. District Court, Eastern District of Texas, on lawyer advertising, for Texans Against Censorship, Inc., 1995.

For defendants in tort liability litigation, criticizing use of "hedonic" damages.

Congressional Committee, pro bono testimony, on recall of All Terrain Vehicles, 1988.

For the New York Power Authority, before the Nuclear Regulatory Commission on costs and benefits of the Indian Point Nuclear Reactor, 1983.

For the Pharmaceutical Manufacturers Association, before the Health Committee of the Georgia Senate, on bills to regulate pharmaceutical prices, 1994; 1995.

Before the Food and Drug Administration, on direct-to-consumer promotion of pharmaceuticals, sponsored by the Progress and Freedom Foundation, 1995.

For the State on New Mexico, regarding taxation of franchising, in an administrative proceeding.

AFFIDAVITS FILED

Airline Antitrust Litigation, regarding the value of the settlement; cited favorably and found "credible" in *Order* of Marvin H. Shoob, Senior U.S. District Court Judge, 1992

Motion of Bell Atlantic, Bellsouth, NYNEX and Southwestern Bell to vacate the Modified Final Judgment in the AT&T Case, 1994.

For Hoechst Celanese Corporation, in the class action regarding polybutylene plumbing, in Chancery Court for Obion County, Tennessee, regarding the fairness of the \$950 million settlement.

Willmann et al. v. GTE, U.S. District Court, Southern District of Illinois, class action regarding "Inside Wire", on the fairness of the settlement; cited favorable and found "credible" by the Court.

Folkerts et al. v. Illinois Bell Telephone Company and Todt et al. v. Ameritech, class action suits regarding "inside wire", on the fairness of the settlements. (There are no decision as yet in these matters; I had previously worked on liability and damage issues for plaintiffs.)

Eller Media v. City of Milwaukee, for Eller Media on the effects of advertising on smoking in First Amendment suit regarding City of Milwaukee ordinance restricting tobacco advertising on billboards. Settled.

Julian M. Whitaker, M.D. v. Donna E. Shalala, Secretary, regarding first amendment issues in the labeling of Saw Palmetto, a dietary supplement, June 8, 2000

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JULIAN M. WHITAKER, M.D., *et al.*,

Plaintiffs,

v.

DONNA E. SHALALA, Secretary,
United States Department of
Health and Human Services, *et al.*

Defendants.

Civil Action No. 00-0123 (PLF)

FILED

APR 28 2000

Clerk, U.S. District Court
District of Columbia

ORDER

Upon consideration of the parties' Joint Motion for a Stay, the lack of opposition thereto, and the entire record of this case, it is hereby

ORDERED that the joint motion is GRANTED and that this case is STAYED until November 24, 2000.

Dated this 28th day of April, 2000



PAUL L. FRIEDMAN
UNITED STATES DISTRICT JUDGE

Copies to:

Meredith Manning
Assistant United States Attorney
555 Fourth Street, N.W., 10th Floor
Washington, D.C. 20001

Jonathan W. Emord
Emord & Associates, P.C.
1050 17th Street, N.W., Suite 600
Washington, D.C. 20036

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EXHIBIT C

AFFIDAVIT OF JULIAN M. WHITAKER, M.D.

I, Julian M. Whitaker, M.D., declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am one of the health petitioners who filed health claim petitions with FDA seeking approval of the following health claims:

As part of a well-balanced diet, rich in fresh whole fruits and vegetables, daily intake of at least 400 ug of folic acid, 3 mg of vitamin B6, and 5 ug of vitamin B12 may reduce the risk of vascular disease.

As part of a healthy diet low in saturated fat and cholesterol, 400 IU/day of Vitamin E (d- α -tocopherol or dl- α -tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.

As part of a healthy diet low in saturated fat and cholesterol, 100 – 400 IU/day of natural Vitamin E (d- α -tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.

As part of a healthy diet low in saturated fat and cholesterol, 200 – 800 IU/day of synthetic Vitamin E (dl- α -tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.

Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers.

Consumption of fiber may reduce the risk of colorectal cancer.

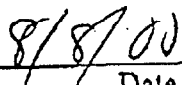
Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease.

0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form.

(collectively "Health Claims")

2. I would like to use the Health Claims on labels and labeling of dietary supplement products.
3. I have read the "Analysis of Economic Impact of FDA Prohibition of Proposed Health Claims" by Economist Paul H. Rubin ("Rubin Report").
4. I cannot afford the \$54 million minimum in estimated cost of research cited in the Rubin Report. Indeed, that sum represents more than 50% of the average annual sales revenue of the company to which I license formulas.
5. Furthermore, I would not be able to recoup the \$54 million because the dietary supplements for which I seek health claim authorization are naturally occurring substances and are not available for patent protection.
6. The costs are thus prohibitive and would make seeking FDA health claim approval economically infeasible.


Julian M. Whitaker, M.D.


Date

AFFIDAVIT OF SANDY SHAW

I, Sandy Shaw, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am one of the health claim petitioners who filed health claim petitions with FDA seeking approval of the following health claims:

As part of a well-balanced diet, rich in fresh whole fruits and vegetables, daily intake of at least 400 ug of folic acid, 3 mg of vitamin B6, and 5 ug of vitamin B12 may reduce the risk of vascular disease.

As part of a healthy diet low in saturated fat and cholesterol, 400 IU/day of Vitamin E (d- α -tocopherol or dl- α -tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.

As part of a healthy diet low in saturated fat and cholesterol, 100 – 400 IU/day of natural Vitamin E (d- α -tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.

As part of a healthy diet low in saturated fat and cholesterol, 200 – 800 IU/day of synthetic Vitamin E (dl- α -tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.

Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers.

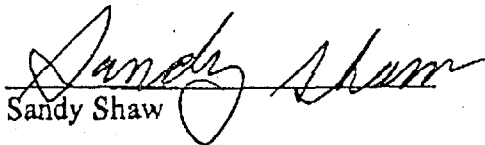
Consumption of fiber may reduce the risk of colorectal cancer.

Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease.

0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form.

(collectively "Health Claims")

2. I would like to use the Health Claims on labels and labeling of dietary supplement products.
3. I have read the "Analysis of Economic Impact of FDA Prohibition of Proposed Health Claims" by Economist Paul H. Rubin ("Rubin Report").
4. I cannot afford the \$58 million minimum estimated cost of research cited in the Rubin Report. Indeed, I estimate that sum represents more than 200% of the average annual revenue of the companies to which I license formulas. It also represents about ^{100,000}~~50,000~~ % of my annual income.
5. Furthermore, I would not be able to recoup the \$58 million dollars because the dietary supplements for which I seek health claim authorization are naturally occurring substances and are not available for patent protection.
6. These costs are thus prohibitive and would make seeking FDA health claim approval economically infeasible.


Sandy Shaw

AUG. 8, 2000
Dated

AFFIDAVIT OF DURK PEARSON

I, Durk Pearson, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am one of the health claim petitioners who filed health claim petitions with FDA seeking approval of the following health claims:

As part of a well-balanced diet, rich in fresh whole fruits and vegetables, daily intake of at least 400 ug of folic acid, 3 mg of vitamin B6, and 5 ug of vitamin B12 may reduce the risk of vascular disease.

As part of a healthy diet low in saturated fat and cholesterol, 400 IU/day of Vitamin E (d- α -tocopherol or dl- α -tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.

As part of a healthy diet low in saturated fat and cholesterol, 100 – 400 IU/day of natural Vitamin E (d- α -tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.

As part of a healthy diet low in saturated fat and cholesterol, 200 – 800 IU/day of synthetic Vitamin E (dl- α -tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.

Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers.


Consumption of fiber may reduce the risk of colorectal cancer.

Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease.

0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form.

(collectively "Health Claims")

2. I would like to use the Health Claims on labels and labeling of dietary supplement products.
3. I have read the "Analysis of Economic Impact of FDA Prohibition of Proposed Health Claims" by Economist Paul H. Rubin ("Rubin Report").
4. I cannot afford the \$58 million minimum estimated cost of research cited in the Rubin Report. Indeed, I estimate that sum represents more than 200% of the average annual revenue of the companies to which I license formulas. It also represents about ^{100,000 to 200} ~~50,000~~% of my annual income.
5. Furthermore, I would not be able to recoup the \$58 million dollars because the dietary supplements for which I seek health claim authorization are naturally occurring substances and are not available for patent protection.
6. These costs are thus prohibitive and would make seeking FDA health claim approval economically infeasible.


Durk Pearson

8 Aug 2000
Date

AFFIDAVIT OF RAYMOND HAMEL

I, Raymond Hamel, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am the General Manager of Pure Encapsulations, Inc. (Pure).
2. Pure is one of the health claim petitioners that filed health claim petitions with FDA seeking approval of the following health claims:

As part of a well-balanced diet, rich in fresh whole fruits and vegetables, daily intake of at least 400 ug of folic acid, 3 mg of vitamin B6, and 5 ug of vitamin B12 may reduce the risk of vascular disease.

As part of a healthy diet low in saturated fat and cholesterol, 400 IU/day of Vitamin E (d- α -tocopherol or dl- α -tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.

As part of a healthy diet low in saturated fat and cholesterol, 100 – 400 IU/day of natural Vitamin E (d- α -tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.

As part of a healthy diet low in saturated fat and cholesterol, 200 – 800 IU/day of synthetic Vitamin E (dl- α -tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.

Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers.

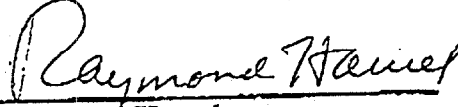
Consumption of fiber may reduce the risk of colorectal cancer.

Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease.

0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form.

(collectively "Health Claims")

3. Pure would like to use the Health Claims on labels and labeling of its dietary supplement products.
4. I have read the "Analysis of Economic Impact of FDA Prohibition of Proposed Health Claims" by Economist Paul H. Rubin ("Rubin Report").
5. Pure cannot afford the \$58 million minimum in estimated cost of research cited in the Rubin Report. Indeed, that sum represents more than 250% of the approximate annual sales of Pure.
6. Furthermore, Pure would not be able to recoup the \$58 million dollars because the dietary supplements for which it seeks health claim authorization are naturally occurring substances and are not available for patent protection.
7. The costs are thus prohibitive and would make seeking FDA health claim approval economically infeasible.


Raymond Hamel

8/9/2000
Dated